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**SYSTEM AND METHOD FOR MATCHING PATIENTS WITH
CLINICAL TRIALS**

FIELD OF THE INVENTION:

5 The present invention relates to a system and method for matching patients with clinical trials. More specifically, the present invention relates to a system and method for quickly and efficiently matching patients with clinical trials and clinical trial sites over a computer network.

10 **BACKGROUND OF THE INVENTION:**

 Many companies sponsor clinical trials for new drugs, medical devices, therapies, or treatment programs. Typical clinical trial sponsors include pharmaceutical companies, biotech companies, medical device companies, clinical research organizations (CRO's), and site management organizations
15 (SMO's). Clinical trials are often an important step before obtaining FDA approval for particular drugs.

 Patients who have been diagnosed with a disease are often in need of finding appropriate clinical trials for new drugs, medical devices, or treatments to treat their disease. Patients with serious diseases may only have weeks or months
20 to live, and thus the ability to find available clinical trials and information about those trials quickly and efficiently is invaluable. Unfortunately today, there is no effective system for quickly matching patients with clinical trials. Doctors are often not aware of all the clinical trials that are being performed in different geographic regions. Clinical trial sponsors have difficulty finding suitable patients
25 for their trials because there is a lack of up-to-date listings of clinical trials, patients are geographically dispersed, many clinical trials require screening large segments of the population, and patients lack insurance coverage. Additionally,

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program 106 which allows terminal to access remote servers and communicate with other terminals via network 116.

Patients and other individuals can access EmergingMed.com server 102 by using patient terminal 108 which is running browser program 110. Healthcare professionals can access EmergingMed.com server 102 by using health care professional terminal 112 running browser program 114. Clinical trial investigators can access EmergingMed.com server 102 by using clinical trial investigator terminal 105. Other individuals can similarly access EmergingMed.com server 102 by using any terminal connected to network 116.

EmergingMed.com server 102 includes a CPU 122 which is running a program which operates the method of the present invention. CPU 122 accesses RAM 118, ROM 120, and data storage device 124. Data storage device 124 can be any magnetic or optical media, or any other medium for storing electronic data. As will be understood by one of skill in the art, EmergingMed.com server 102 can comprise multiple servers working together, and data storage device 124 can similarly comprise multiple storage devices.

Data storage device 124 contains a database 142. Database 142 contains information organized into records. Some exemplary records are shown in FIG.

1. Disease/sub-disease records 126 contain information related to specific diseases. These records are organized both by disease and sub-disease. An example of a disease is "cancer" and an example of a sub-disease is "skin cancer." Disease/sub-disease records 126 contain information about the disease such as description of the disease, symptoms, treatment, history, and other pertinent information. Each disease/sub-disease record 126 also includes links to other related records in database 142 such as drug records 128 (e.g. drugs used to treat the disease), content records 130, clinical trial site records 132, question records

134, and device records 136. The links between records are described in more detail with respect to FIG. 3.

Drug records 128 contain information about various drugs. Such information includes the purpose of the drug, compound name, generic name, brand names, instructions for taking the drug, warnings, side effects, and any other pertinent drug information. Each drug record 128 contains links to other records in database 142.

Content records 130 contain various kinds of content such as newspaper and journal articles, research reports, frequently asked questions, standard therapies, alternate medicine, case studies, and various other types of medical information that would be of interest to someone seeking information about diseases and treatments. Content records 130 contain links to other records in database 124.

Clinical trial site records 132 contain information pertaining to various clinical trial sites. Clinical trials are performed for various reasons such as to test the efficacy of a new drug, a new medical device, or a new therapy. Clinical trials are often performed prior to obtaining FDA approval. One clinical trial may take place at multiple clinical trial sites. Each clinical trial site preferably has its own record in clinical trial site records 132. A clinical trial is conducted by an investigator on behalf of a sponsor at a clinical trial site.

Clinical trial site records 132 contain information about the clinical trial site such as the sponsor's name and information, investigator's name and information, location, number of patients admitted, number of patients allowed, open or closed status, drug or device being tested, names of staff, duration of trial, phases of the trial, purpose of the trial, trial methodology, and any other information relevant to the clinical trial being performed. Clinical trial site records 132 contain links to other records in database 142.

Question records 134 contain questions that are asked to users who are seeking to join clinical trials. As explained in detail with respect to FIG. 2, patients who are seeking to join clinical trials are asked a series of questions about their disease, their prior treatment, and their medical history. The answers to these questions are used to build a patient profile. If the answers to these question match the acceptance criteria for a specific clinical trial, then the patient becomes eligible to apply for that clinical trial. Question records 134 contain links to other records in database 142.

Device records 136 contain information about various medical devices such as the device manufacturer name, the diseases and conditions treated, instructions for using the device, warnings, and other pertinent device information. Device records 136 contain links to other records in database 142.

User registration records 140 contain user information about the various users authorized to access EmergingMed.com server 102. User registration records 140 contain information such as user name, user ID number, login name, password, access privileges, customized user preferences, mail accounts, links to patient profiles, and any other similar user information.

Patient profile records 138 contain various types of medical information about patients including their gender, age, medical histories, diseases, symptoms, and any other relevant medical information. Patient profile records are created by asking the patient a series of questions. The responses are used to build the patient's profile. The responses can be entered by a health care professional or by the patients themselves.

In a preferred embodiment of the invention, patient profile records 138 do not contain the user's name, but instead only contain the user's ID number. In other words, the patient's medical information is kept separate from the patient's identifying information. This maintains the user's medical privacy and

anonymity. As will be described in more detail with respect to FIG. 2, every patient is assigned a user ID number. The user's name and identifying information is stored in the user's registration record 140 along with the user's ID number. The patient's medical information is stored in a patient profile record 5 138 along with the patient's user ID number. In this way, the patient's profile record 138 can be sent to a third party without revealing the patient's identity to the third party. In this way, EmergingMed.com has access to the patient's identifying information, but third parties do not. Additional records can be added to database 142 for various other purposes. Also, the organization of the records 10 shown in FIG. 1 is by example only, and different organizations and groupings of records is possible.

FIG. 2 depicts a flowchart illustrating a method of matching a patient with available clinical trials. In step 200, a user registers with the EmergingMed.com web site. The user could be a patient, a health care professional such as a doctor, 15 a representative from a clinical trial sponsor, an investigator, a representative from a health care facility or clinical trial site, or any other individual or entity involved in the clinical trial process.

When a user registers, the user selects a user name and a password. The user can also submit an e-mail address. This information is stored in a user 20 registration record 140. The user is also assigned a user ID number. This user ID number is attached to the user's profile records/medical information in order to keep the user-patient's identity anonymous.

In step 201, a user interested in searching for available clinical trials accesses the EmergingMed.com web site by entering an appropriate URL such as 25 <http://www.emergingmed.com>. The user then clicks on a link or a series of links that directs the user to the clinical trial search process.

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When the user is presented with questions, the user is also presented with a group of answer options. The user can click on one or more of the answer options to respond to the question (some questions only allow one answer option to be selected, whereas other questions allow multiple answer options to be selected).

Preferably the questions asked to the patient, and the answer options provided to the patient, are such that a computer software program can evaluate and score the answers to the questions, rather than having a human being evaluate the answers. For example, one type of question that is easy to evaluate and/or score by a computer program is a question that allows the patient to choose one or more answers from a set of discrete multiple-choice answers. This type of question is very easy for a computer to evaluate and/or assign a score. As another example, if the patient is required to enter a numerical number, such as enter the patient's blood pressure, height or weight, this is also very easy for a computer to evaluate and/or assign a score. However, if the patient were asked "Please describe your pain" and then the patient were allowed to enter a text message, then a computer would have a difficult time evaluating this answer. A human would have to read the answer and evaluate the answer.

Some example questions are presented as follows:

- Please select any or all prior cancer treatments (followed by a list of treatments, patients can click on any treatments they have had).
- How many times did you have surgery?
- Please select all dates that correspond to your surgeries (followed by a list of dates that the patient can click on).
- Select all surgical procedures performed to date.
- Was your surgery followed by (followed by a list of choices)?.
- Was your surgery proceeded by (followed by a list of choices)?

preferably done at the trial site level, not the trial level. For example, a drug manufacturer may be sponsoring a clinical trial for a new drug at many trial sites around the country. The patient's profile is compared to each individual trial site to determine whether the patient prequalifies for that individual trial site.

- 5 Different trial sites for the same trial could have different acceptance criteria. For example, a particular trial site may be limited to patients living within twenty miles of the trial site.

One method that can be used to determine whether a patient prequalifies for a particular trial site, is that the patient prequalifies for a trial site only if the patient meets all of the acceptance criteria for that specific trial. For example, a trial site could require that a patient must be female between the ages of 30-40 who has breast cancer, does not drink alcohol, and lives within twenty five miles of New York City. If the patient meets all of these criteria, then the patient will be prequalified for that trial site.

- 15 An alternative method of prequalifying patients is to calculate a score based on the answers given by the patient. For example, the score could simply be the number of criteria met by the patient. More complicated algorithms could also be used to generate a score. For example, the score could include the patient's blood pressure divided by two, plus three times the patient's age, and so on. The patient would then qualify only if the score exceeded or was less than a predetermined threshold or within certain predetermined threshold limits. There can also exist a combination of a score threshold, and criteria which must be satisfied in order to qualify. For example, in order to qualify for a particular trial site, patients could be required to be female, over 35, and have a score over 253
- 20
- 25 where the score is based on a number of other factors.

Some examples of acceptance criteria that can be used include: the patient must be within a certain age range, must be female, must live within a certain

geographic region, must have skin cancer, must have not had previous surgery, must have been diagnosed with cancer within the last six months, cancer must not have spread to other body organs, etc.

- As mentioned previously, the users are required to enter answers to patient profile questions in a format that is suitable for evaluation by a computer program process. Optionally, the user could be provided with a combination of questions: some questions requiring answers in numerical or multiple choice format, and some questions requiring a text description to be entered by the user. The former type of questions are used to perform the automatic prequalification of the patient.
- 10 The descriptive answers entered by the patient could later be sent to the clinical trial site for evaluation by clinical trial site personnel.

- Acceptance criteria for clinical trial sites are typically provided by the clinical trial sponsors. Alternatively, the acceptance criteria could also be provided by clinical trial site investigators. One method of providing acceptance
- 15 criteria to EmerginMed.com is to have the clinical trial sponsor or clinical trial investigator provide acceptance criteria to server administration personnel at EmergingMed.com. The acceptance criteria could be sent to EmergingMed.com by regular mail, by fax, by e-mail, over the telephone or any other communication method. The EmergingMed.com server administration personnel then program
- 20 EmergingMed.com server 102 to use the acceptance criteria to qualify patients for that particular clinical trial.

- An alternative method is to allow clinical trial sponsors and/or clinical trial investigators to be provided with access privileges to the EmergingMed.com server 102. The sponsors or investigators could then access the
- 25 EmergingMed.com web site via network 116. A link or group of links would direct the sponsors or investigators to a web page that allows the sponsors/investigators to automatically enter acceptance criteria. Database 142 is

scaleable and updateable by EmergingMed.com 102 personnel. In some instances, other parties such as clinical trial sponsors and investigators can be given access privileges (as described above) to enter data such as acceptance criteria, questions, answers, etc. The static and dynamic questions asked to
5 patients to build their patient profile can be updated and/or supplemented frequently to reflect new medical developments, trial site selection criteria, new clinical trials, amendments to clinical trial protocols, and other developments.

Users can also be informed of the number of trials for their disease for which the patient does not qualify, or how many trials are currently closed, or
10 potentially if there is a waiting list available for which the patients can sign up. For example, the user could be informed that for skin cancer there are currently ten trials available and the patient qualifies for three of those ten.

After the system has made a preliminary determination of whether the patient prequalifies for any clinical trials, in step 210 the system can provide
15 targeted questions specific to each clinical trial for which the patient has preliminarily qualified. Once the system has received responses to these targeted questions, then in step 212 the system makes a final determination as to whether the patient prequalifies for any of the clinical trials based on the user's responses to the targeted questions.

20 In step 214, if the patient prequalifies for any clinical trials, the patient is then provided with an application to fill out. The patient is allowed to submit an-line application for each trial site for which he or she qualifies. The patient's applications and medical profile are submitted online to EmergingMed.com server 102. Alternatively, the patients could submit their applications and profiles by
25 other methods such as by mail or by facsimile.

In step 216, the patient's applications are forwarded along with the patient's medical profile to the appropriate trial site investigators or designated

staff. The applications can be submitted to the trial site online, or alternatively, by other methods such as mail or facsimile. As described previously, the patient's medical profile and application preferably does not contain the patient's name, social security, and other identifying information. The patient's medical profile and application only include a patient ID number. In this way, the patient's privacy is protected in accordance with government regulated confidentiality standards. A copy of the patient's application/profile, a summary of the patient's application/profile, or a notification could optionally be sent to the trial sponsor in addition to the trial site.

10 As an alternative to submitting applications to the trial sites via EmergingMed.com web server 102, the applications could alternatively be submitted directly by the patient to the trial site investigators or staff. However, it may be preferable to send all information to the trial site via EmergingMed.com server 102 in order to maintain the privacy of patients' identity.

15 Another method of sending the patient's application and profile to the trial site investigator is as follows. The trial site investigator or contact person has a designated "mailbox" in a message center on EmergingMed.com server 102. The patient therefore sends a message to the investigator/contact person containing the application and profile. This message is then stored on the EmergingMed.com server 102 and can be retrieved by the investigator/contact person.

20 In step 220, the patient is notified whether he or she has been successfully prescreened or rejected for the clinical trial site which the patient has applied. The patient can be telephoned or e-mailed or contacted by other means. Alternatively, the patient can access the EmergingMed.com web site and check his or her status. If the patient has successfully prequalified for a clinical trial site, the patient can be provided with contact information at the trial site. The patient can then contact the appropriate person at the trial site (either through a

Trial sponsor to investigator matching involves matching a clinical trial sponsor with an investigator suitable for conducting the trial. For example, a drug company might be interested in finding a researcher with 20 years of experience researching breast cancer treatment in the Milwaukee area. Investigator to trial site matching involves matching investigators with trial sites that are looking for investigators with particular qualifications. What all of these methods share in common is that the EmergingMed.com server 102 finds matches between matching parties and performs an initial layer of prequalification or prescreening before bringing the parties together.

FIG. 3 depicts a block diagram illustrating some exemplary links between various records in data storage device 120. These links allow a user to navigate the web site and efficiently find medical information relevant to their particular medical condition. The user can also search for relevant information by entering keyword queries. For example, a user searching for particular information about a particular disease would enter the name of a disease and sub-disease such as "cancer/skin cancer." This would retrieve disease/sub-disease record 300 for skin cancer. Disease/sub-disease record 300 would contain information about skin cancer which would be provided to the user. When the user accesses disease/sub-disease record 300, the user is provided with all of the information contained in record 300 as well as links to records 302, 304, 305, and 306. The user can then click on one of these links to access the linked record.

Disease/sub-disease record 300 contains links to related drug/device records 302. These drug/device records are associated with drugs and medical devices used to treat the disease/sub-disease associated with disease/sub-disease record 300. The drug/device records 302 contain information about their associated drug or device such as instructions for taking a drug or using a medical device, warnings, side effects, and similar information.

Although the present invention has been described in terms of various embodiments, it is not intended that the invention be limited to these embodiments. Modification within the spirit of the invention will be apparent to those skilled in the art. The scope of the present invention is defined by the

5 claims that follow.

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